APR 0 3 2014

510(k) Summary
for
CRYOTOP®SC

1. Submission Sponsor

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2. Submission Correspondent

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Contact: Richard VINCINS, Vice President, QA
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3. Date Prepared

1 April 2014

4. Device Identification

Trade/Proprietary Name:	Cryotop®SC
Common/Usual Name:	Cryopreservation storage device
Classification Name:	Assisted Reproduction Labware
Classification Regulation:	884.6160
Product Code:	MQK
Device Class:	Class II
Classification Panel:	Obstetrics/Gynecology

5. Legally Marketed Predicate Device(s)

Cryo Bio System, HSV Straw, K092398

6. Device Description

CryotopSC is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 4-8 cell and blastocyst stage embryos. Extracting embryos from the body can be costly and burdensome process for the patient to go through multiple extraction procedures. As part of the vitrification procedure, the cells to be stored are loaded on the tip of the CryotopSC device for subsequent storage.

The CryotopSC device is composed of an ABS handle shaft with a PET fine tip and a straw enclosure. The fine tip has a flat film area for loading embryos. The CryotopSC device has a "straw" enclosure system for when the unit is placed in the liquid nitrogen. The straw cap is designed to be heat sealed by the user. The straw cap has a weight at the distal end to place the straw cap and the shaft inside of the cap in a correct position in the liquid nitrogen. The CryotopSC device is provided sterile and is for single use only. The CryotopSC device has been designed to maintain the integrity of the human embryos through the freezing and thawing process.

The Aluminum Block is required for use with the CryotopSC device for the vitrification and thawing process and is sold separately. The Aluminum Block is to be used with the CryotopSC device to prevent liquid nitrogen from entering the straw and to assist in stabilizing the manipulation of the straw.

The CryotopSC device conforms to product quality test specifications of our company: appearance, dimension, durability, tensile strength, colorfastness, endotoxin and Mouse Embryo Assay. The sterilization dose of CryotopSC is validated by sterilization validation to maintain the sterility of the device through anticipated storage and handling.

7. Indication for Use Statement

The Cryotop®SC is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 4-8 cell and blastocyst stage embryos.

8. Substantial Equivalence Discussion

The following table compares the CryotopSC to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**KITAZATO BioPharma Co., Ltd.**	**Cryo Bio System**
Trade Name	Cryotop®SC	HSV Straw
510(k) Number	Not assigned	K092398
Product Code	MQK	MQK
Regulation Number	884.6160	884.6160
Regulation Name	Assisted Reproduction Labware	Assisted Reproduction Labware
Indications for Use:	The CryotopSC is a cryopreservation storage device that is intended for use in	The HSV Straw is a cryopreservation storage device that is intended for use in vitrification procedures to

Manufacturer	KITAZATO BioPharma Co., Ltd.	Cryo Bio System
Trade Name	Cryotop®SC	HSV Straw
	vitrification procedures to contain and maintain human 4-8 cell and blastocyst stage embryos.	contain and maintain human 4-8 cell and blastocyst stage embryos.
Overall Design	The CryotopSC is designed to contain, freeze and maintain embryos. The device consists of a two piece assembly comprised of the main part containing the fine tip film area and the "straw." The straw is designed to be sealed. The straw is weighted to allow proper alignment in the storage container. The CryotopSC device is packaged in a single barrier sterilization pouch.	The HSV Straw is designed to contain, vitrify and maintain embryos. The device consists of 3 parts: a resin straw, a capillary tube with a pre-formed gutter attached to a colored handling rod, and a blue plastic insertion device. The straw is designed to be sealed. The HSV Straw is packaged in a peel off blister pack.
Method of Action	Vitrification Method	Vitrification Method
Sterile	Radiation	Radiation
Cooling Rate	3,000°C/min	2,900°C/min
Rewarming Rate	44,000°C/min	25,000°C/min
Material Composition	PET, ABS, Polypropylene	Medical Grade Styrene-Butadiene Copolymer, Ionomeric resin
Contact with Warming Medium	The tip (film) and the shaft of CryotopSC are taken out from the straw. Directly immerse the tip (film) into thawing solution.	The curved spatula, containing the cryopreserved embryo, is immersed in thawing solution where thawing and dilution in the thawing solution occur simultaneously.
Performance Testing of Device	Passed	Passed
Mouse Embryo Test Passed	Yes	Yes
Sterility Validation Passed	Yes	Yes

9. Non-Clinical Performance Data

The CryotopSC device has been evaluated for the cooling/warming rate, mechanically tested, sterility tested, and mouse embryo assay supporting that all the specifications have met the acceptance criteria for the device. The following testing has been performed to support substantial equivalence:

Performance Testing

- Cooling Rate Testing: Cooling rate of 3,000 °C/min passed
- Warming Rate Testing: Warming rate of 44,000 °C/min passed
- Dimensional Testing: Passes outer diameter and length according to specifications
- Mechanical Tensile Testing: Tensile strength to withstand 5N
- Endotoxin Testing: Endotoxin values conform to the value ≤0.5 EU/device
- Sterility Testing: No microbial growth from sterility testing
- Mouse Embryo Assay: ≥80% of 1-cell control embryos develop at 96 hours

Note: The performance testing, Mouse Embryo Assay (MEA), and sterility test are all performed on samples from routine manufactured lots; a Certificate of Analysis is provided with each lot of CryotopSC device.

The CryotopSC device passed all testing and supports the claims of substantial equivalence. The CryotopSC meets all the requirements for overall design, sterilization, functional, and mouse embryo assay testing confirms that the output meets the design inputs and specifications. The CryotopSC passed all testing stated above as shown by the acceptable results obtained.

The CryotopSC device complies with the applicable voluntary standards for sterilization. The device passed all the testing in accordance with national and international standards.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing. The validation testing of sterility testing and mouse embryo testing was found to acceptable and supports the claims of substantial equivalence.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

KITAZATO BioPharma's Cryotop®SC, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2014

KITAZATO BioPharma Co., Ltd.
% Richard A. VINCINS, CQA, CBA, RAC (US, EU)
Vice President, QA
Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701

Re: K140072
Trade/Device Name: Cryotop®SC
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted reproduction labware
Regulatory Class: II
Product Code: MQK
Dated: January 10, 2014
Received: January 13, 2014

Dear Richard A. VINCINS,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K140072

Device Name
Cryotop®SC

Indications for Use *(Describe)*
The Cryotop®SC is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain human 4-8 cell and blastocyst stage embryos.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Benjamin R. Fisher -S
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